

### REMARKS

Applicant respectfully requests reconsideration. Claims 1-13, 20, 22 and 74-77 were previously pending in this application. Claims 1, 4, 9, 10, 13 and 20 have been amended. Support for the claim amendments can be found, for example, on pages 2-3 of the specification and in the claims as originally filed. As a result, claims 1-13, 20, 22 and 74-77 are pending for examination with claims 1, 9 and 20 being independent claims.

No new matter has been added.

### Rejections under 35 U.S.C. §112

The Examiner has rejected claims 1-13, 20, 22 and 74-77 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant respectfully traverses this rejection. First, the rejection is based in part on the assertion that the term “Group A” is uncertain as to meaning and scope. However, it is noted that the specification clearly indicates what is intended by the term. Since the specification clearly provides what is meant by the term, and the claims are read in light of the specification, the use of the term is not indefinite. However, in the interest of expediting the prosecution of this application, Applicant has amended claims 1, 9 and 20 to recite Groups A structures (A)-(N) from page 3 of the specification.

Second, the rejection is also based on the assertion that it is uncertain as to what agents function as a “bulking agent”, “depilatory agent” and “film forming agent”, respectively. The meaning of all of these terms and the agents that are encompassed by their recitation is known to one of ordinary skill in the art based on their plain meaning. In addition, the specification provides definitions as well as extensive examples of members for each of these classes of agents. For example, on page 57 of the instant specification, it is taught that bulking agents can be agents that can be added to hair or nails to provide ‘bulk’ and strength. As another example, on page 58, the specification provides that bulking agents can be used as hair conditioning or hair fixative agents. A number of examples of such bulking agents, respectively, are then provided. In regard to depilatory agents, the term is defined in the specification (See, e.g., page 15, line 19, and page 57, line 12) as a hair removal agent. Extensive examples are also provided. Finally, in regard to film forming agents, such agents are defined as agents which produce a

continuous film on skin, hair or nails upon application (See, e.g., page 69 of the specification). Again, extensive examples are provided. Therefore, based on the plain meaning of the terms and the definitions and extensive examples provided in the instant specification, one of ordinary skill in the art would understand the meaning and scope of the terms as recited in the rejected claims.

Third, the rejection is also based on the contention that it is unclear as to what is meant by “high affinity noncovalent coupling” (used in reference to a class of agents, components of a high affinity noncovalent coupling, in rejected claim 2). Based on the plain meaning of this term, one of ordinary skill in the art will readily recognize that the term is meant to encompass any molecule that binds to another molecule through noncovalent means with high affinity. This means that the two components noncovalently and preferentially (over other molecules) bind to each other. Such noncovalent high affinity binding pairs are well known and are easily recognizable by one of ordinary skill in the art. Examples of high affinity noncovalent coupling pairs include biotin-avidin and biotin-streptavidin.

Fourth, the Examiner has based the rejection in part on the use of “OPAA” and “OPA” and indicates that the full name of these abbreviations should be used. Applicant has amended the claims but does so without conceding the correctness of the Examiner’s rejection on this basis.

Fifth, the Examiner has rejected claims 8 and 76 as being confusing because of unclear antecedent basis for “dihydroxyacetone”. It is true that this term does not appear in claims 1 and 9 from which claims 8 and 76 depend, respectively; however, this is not improper antecedent basis. Claims 8 and 76 further limit what the reactive moieties,  $X_1$  and  $X_2$ , can be.  $X_1$  and  $X_2$  previously appear in claims 1 and 9, and claims 8 and 76 that depend therefrom, respectively, merely define that these reactive moieties can be dihydroxyacetone.

Sixth, the Examiner has rejected claim 9 for the lack of clear antecedent basis for “said crosslinking”. Applicant has amended claim 9 accordingly.

Seventh, this rejection is also based on the assertion that it is uncertain as to the meaning and scope of “integument”. Applicant maintains that “integument” is a term of art that would be understood by one of ordinary skill. Integument refers to a covering or coat, such as the skin of an animal or the membrane enclosing an organ. Examples of such a covering or coat are provided in the specification (See, e.g., page 16, line 8) and include skin, nails, hair, mucous membranes and the surface of the eye. Therefore, because the term is known to those of

ordinary skill in the art, and while not necessary, examples are provided in the instant specification, Applicant maintains that the meaning and scope of integument is not uncertain to one of ordinary skill in the art.

Finally, the Examiner has rejected claim 10 for the recitation of “and” between “hair” and “nails” of the Markush group, as “and” should only be recited before the last member of the Markush group. Without conceding the correctness of the rejection on this basis, Applicant has amended the claim.

Accordingly, based on the arguments and claim amendments provided above, withdrawal of the rejection of claims 1-13, 20, 22 and 74-77 under 35 U.S.C. §112 is respectfully requested.

#### Rejections Under 35 U.S.C. §102

The Examiner rejected claims 1, 2, 5-7, 9-11, 20, 74, 75 and 77 under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,267,957 B1 to Green et al.

Applicant respectfully traverses this rejection. U.S. Patent No. 6,267,957 neither anticipates or makes obvious the compounds of the rejected claims. Applicant notes that the claimed invention comes from the surprising discovery that certain compounds, such as those of Applicant’s claims, are particularly desirable for attaching agents to proteinaceous material. The teachings of Green et al. cited by the Examiner, however, do not explicitly provide and would not necessarily lead one of ordinary skill in the art to create such compounds.

The compounds according to the cited teachings of Green et al. are conjugates of a linking molecule (e.g., polylysine or polyglutamine) and an agent, where the attachment of the linking molecule and the agent can be facilitated by providing functionalized groups to these components and/or linkers between them. Also provided by Green et al. are numerous linkers, such as bis(sulfosuccinimidyl) suberate or disuccinimidyl suberate for use in attaching the linking molecule and agent. The compounds of Applicant’s claims, however, are directed to compounds having a structure as provided in Formula I. This compound comprises at the minimum an agent (A) attached to an organic linker or bond ( $L_1$ ), which linker or bond is attached to a reactive moiety ( $X_1$ ). The reactive moieties are limited to specific molecules, which include N-hydroxy-succinimide, N-alkyl maleimide and the moieties of Group A.

Firstly, Applicant maintains that the cited teachings of Green et al. are not anticipatory. In order for a reference to anticipate a claim, the reference must provide all of the limitations of that claim. The teachings cited by the Examiner from Green et al., however, do not provide all of the limitations of the rejected claims. For example, the cited teachings do not provide the reactive moieties of Applicant's claims. The reactive moieties of the rejected claims are limited to specific molecules, and it is not clear from the teachings cited by the Examiner and explanation provided in the Office Action for this rejection how such specific reactive moieties are provided in Green et al.

Secondly, Applicant maintains that the cited teachings of Green et al. do not make obvious the rejected claims. Again, as stated above, the teachings cited from Green et al. do not provide the reactive moieties of the rejected claims. In addition, the cited teachings and arguments presented by the Examiner do not demonstrate that one of ordinary skill in the art could or would modify Green et al. to produce Applicant's compounds. These cited teachings at best provide that the agent and linking molecule of Green et al. may be provided with functionalized groups (either one or both of the components could be functionalized), may have a linker interposed therebetween or may have some combination of functionalized groups and linkers. Out of all of the compounds that may be created from such teachings, it is not clear from the Examiner's rejection that one of ordinary skill in the art could or would create the compounds of Applicant's claims.

The teachings cited by the Examiner do not demonstrate that one of ordinary skill in the art could or would create a compound whereby an agent is attached to a reactive moiety via a linker or bond and that the reactive moiety is one of the specific molecules provided. Furthermore, the cited teachings do not provide one of ordinary skill with the necessary motivation or suggestion to modify the teachings to obtain the compound of Applicant's claims, if *arguendo* they could be construed to provide the components of the compound of Formula I, which Applicant does not believe is the case. Without the necessary teachings to guide one of ordinary skill in the art to modify the teachings cited by the Examiner of Green et al., such that one of ordinary skill in the art could obtain the compound of the rejected claims, the obviousness rejection also fails due to the lack of expectation of success that Applicant's compounds would be created.

Therefore, based on the arguments provided above, withdrawal of the rejection for anticipation and obviousness is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner has also rejected claim 22 under 35 U.S.C. §103(a) as being unpatentable over Green et al. for the alleged disclosure of a kit; claims 3, 4, 12 and 13 over Green et al. in view of Cheng et al. (U.S. Patent NO. 6,080,566) for the supposed teaching of OPAA anhydrolase and OPA anhydrase; and claims 8 and 76 over Green et al. in view of Fusaro (U.S. Patent No. 3,920,808) for the supposed teaching of dihydroxyacetone.

Applicant respectfully traverses all of the respective rejections of the above-recited claims for obviousness. In light of the arguments presented above, Applicant believes these rejections are now moot. In addition, for each of these rejections, the Examiner has failed to explain why one of ordinary skill in the art would modify the teachings of Green et al. alone or combine the teachings of Green et al. with the other cited references. Furthermore, the Examiner has also not demonstrated why one of ordinary skill in the art would have the expectation of success in obtaining the compounds of the rejected claims based on Green et al. alone or in combination with the other cited references.

Accordingly, withdrawal of this rejection is respectfully requested.

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- 12 -

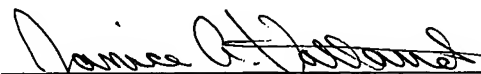
Art Unit: 1651

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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